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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MUTUAL PHARMACEUTICAL COMPANY, INC.; AR SCIENTIFIC, INC.; and AR HOLDING COMPANY, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
WEST-WARD PHARMACEUTICAL CORPORATION,	)	
Defendant.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Mutual Pharmaceutical Company, Inc. ("Mutual"), AR Scientific, Inc. ("AR Scientific') and AR Holding Company, Inc. ("AR Holding") (collectively "Plaintiffs"), as their Complaint for a declaratory judgment of patent infringement against Defendant West-Ward Pharmaceutical Corporation ("West-Ward"), allege the following:

THE PARTIES

1. Mutual Pharmaceutical Company, Inc. ("Mutual") is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124. Mutual manufacturers prescription drugs, including an oral single-ingredient colchicine tablet sold under the name COLCRYS®, which is used to treat and prevent gout flares.

2. AR Scientific, Inc. ("AR Scientific") is a Delaware corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19121. AR Scientific markets and sells COLCRYS®.

3. AR Holding Company, Inc. ("AR Holding ") is a Delaware corporation with its principal place of business at 1105 North Market Street, Suite 1300, Wilmington, Delaware 19801.

4. Plaintiffs are informed and believe, and based thereon allege, that West-Ward is a Delaware corporation with its principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724. West-Ward 's principal business is marketing and selling pharmaceutical products.

JURISDICTION AND VENUE

5. This is an action seeking declaration of patent infringement arising under the Declaratory Judgment Act, Title 28 United States Code §§ 2201, 2202, and the patent laws of the United States, Title 35, United States Code.

6. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because this action involves an actual controversy concerning West-Ward's imminent future infringement of the patents-in-suit.

7. This Court has personal jurisdiction over West-Ward because among other reasons, it has its principal place of business in New Jersey, it has extensive contacts with the State of New Jersey, the causes of action asserted in this Complaint arise out of those contacts, and West-Ward regularly does business in this district.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b) & (c), and 1400(b).

THE PATENTS-IN-SUIT

9. AR Holding is the lawful owner of all right, title, and interest in and to the following United States patents, including all right to sue, seek declaratory relief, and to recover for infringement thereof, which patents contain one or more claims covering the method of use of and packaging of COLCRYS®.

A. United Sates Patent Number 7,619,004 ("the '004 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," a copy of which is attached hereto as Exhibit A and incorporated herein by reference as though set forth in full, was duly and legally issued November 17, 2009, naming Matthew Davis as the inventor.

B. United States Patent Number 7,601,758 ("the '758 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS IN THE TREATMENT OF GOUT FLARES," a copy of which is attached hereto as Exhibit B and incorporated herein by reference as though set forth in full, was duly and legally issued October 13, 2009, naming Matthew Davis as the Inventor.

C. United States Patent Number 7,820,681 ("the '681 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit C and incorporated

herein by reference as though set forth in full, was duly and legally issued October 26, 2010, naming Matthew Davis as the inventor.

D. United States Patent Number 7,915,269 ("the '269 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit D and incorporated herein by reference as though set forth in full, was duly and legally issued March 29, 2011 naming Matthew Davis as the inventor.

10. The '004, '758, '681, and '269 Patents are referred to collectively as the "Patents."

BACKGROUND

I. COLCRYS® is the Only FDA Approved Drug of its Kind

11. COLCRYS® is used to prevent and treat gout flares. Gout is a type of severe arthritis typically characterized by extremely painful "flares" (severe and sudden attacks of pain, redness, inflammation and tenderness in joints) resulting from a build-up of uric acid. COLCRYS® is the only product approved by the FDA to both treat and prevent these painful gout flares.

12. In 2009, as a result of Mutual's research, the United States Food and Drug Administration ("FDA") approved Mutual's oral single-ingredient colchicine product COLCRYS®. Through its extensive research, Mutual discovered important information about colchicine, including previously unknown information concerning safety and efficacy, tolerability, dangerous side effects and interactions with other medicines.

13. To date, COLCRYS® is the only oral single-ingredient colchicine product approved by the FDA and the only FDA-approved product of any kind for the treatment and prevention of gout flares.

14. The product insert accompanying COLCRYS® recites various methods of use protected by the Patents.

II. West-Ward's Unapproved Colchicine Tablets

15. West-Ward claims that since 1972, it has manufactured and sold over one billion unapproved oral single-ingredient colchicine tablets, meaning that FDA has never approved these tablets for sale.

16. In 2006, the FDA undertook a new drug safety initiative to remove unapproved drugs from the market to ensure that all marketed drugs meet modern standards for safety, effectiveness, quality and labeling. FDA found that "unapproved drugs represent a public health threat because consumers wrongly assume that these widely marketed and available drugs are approved and have been found to be safe and effective by the FDA," despite their having completely bypassed the FDA's rigorous drug approval processes. Single ingredient colchicine was part of this FDA drug safety initiative.

17. West-Ward failed to heed FDA's drug safety initiative and continued to manufacture and sell oral single-ingredient colchicine tablets, including a 0.6 mg tablet.

18. On October 1, 2010, FDA announced its intent to take enforcement action against unapproved oral single-ingredient colchicine products and manufacturers like West-Ward because this unapproved drug was a threat to public safety. 75 FR 60768-01. West-Ward at the time was a manufacturer of unapproved oral single-ingredient colchicine products.

19. In October 2010, West-Ward ceased manufacturing its unapproved oral single-ingredient colchicine tablet.

III. The Food, Drug and Cosmetic Act and the Prescription Drug User Fee Act

20. The Federal Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules governing the FDA's approval of prescription drug applications and requires applicants to prove a drug is both safe and effective.

21. There are three types of drug applications: (a) New Drug Applications ("NDAs"); (b) Section 505(b)(2) Applications, which are a type of NDA; and (c) Abbreviated New Drug Applications ("ANDAs").

22. To obtain approval for a new drug, an applicant must submit an NDA with clinical data demonstrating safety and efficacy. Once approved, the drug is termed a Reference Listed Drug ("RLD").

23. An applicant submits a Section 505(b)(2) application when it seeks approval for a drug that represents a change from the RLD (such as a different dose). The applicant must submit full safety and efficacy reports like in a full NDA, but can rely on safety and efficacy information from studies it conducted as well as studies conducted by others.

24. An applicant seeking approval of a drug that is a duplicate of an already approved RLD generally must submit an ANDA and rely on the RLD's safety and efficacy information.

25. The Prescription Drug User Fee Act, 21 U.S.C. § 379 *et seq.*, generally provides that FDA will render a decision on an NDA, including a 505(b)(2) application, no later than 10 months after submission of the application to FDA ("PDUFA date"). The PDUFA date is the date by which the applicant can expect the FDA to render its decision on the application.

IV. FDA Approval of West-Ward's Oral Single-Ingredient Colchicine Tablet is Imminent

26. On or about September 1, 2010, West-Ward submitted a Section 505(b)(2) application ("Application") for a 0.6 mg oral single-ingredient colchicine tablet ("West-Ward Tablet"). The West Ward Tablet has the same active pharmaceutical ingredient, route of administration, dosage form and strength as COLCRYS®.

27. Because West-Ward submitted the Application on or about September 1, 2010, the PDUFA date for the Application is approximately July 1, 2011.

28. On a March 18, 2011 call with financial analysts, West-Ward stated that it has been in constant contact with FDA about the Application and has satisfied all of FDA's demands to obtain approval of the Application:

> Pretty much right after submission [of the Application] the FDA has been in constant contact with us, in constant contact even with the API [Active Pharmaceutical Ingredient] manufacturer. There's a lot of pressure on the agency for approval of this. Right now, we've satisfied all of the demand, and its pending with the agency.

29. On March 23, 2011, West-Ward's outside FDA counsel notified Mutual's outside FDA counsel that FDA approval of the West-Ward Tablet was imminent.

30. Plaintiffs are informed and believe, and based thereon allege, that West-Ward's belief that FDA approval of the Tablet is imminent is based, at least in part, on its recent communications with FDA.

31. Accordingly, Plaintiffs are informed and believe, and based thereon allege, that FDA approval of West-Ward's Application is imminent and will occur on or before July 1, 2011.

32. Plaintiffs are informed and believe, and based thereon allege, that FDA did not require West-Ward to perform any clinical studies in order to obtain approval of the Application, which allowed FDA to conduct an abbreviated review of the Application because FDA does not

have to undertake the time consuming effort required to critically analyze clinical studies to grant approval.

V. West-Ward Intends to Manufacturer, Advertise, Promote and Sell the West-Ward Tablet at the Earliest Opportunity Once it Receives FDA Approval.

33. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has made concrete plans to manufacture, advertise, promote, market, offer to sell and sell the West-Ward Tablet when it receives FDA approval and/or at the earliest opportunity thereafter.

34. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has developed and approved comprehensive business plans that will allow it to manufacturer, offer to sell and sell the West-Ward Tablet when it receives FDA approval and/or at the earliest opportunity thereafter.

35. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has developed a marketing and advertising strategy to promote the sale of the West-Ward Tablet, and West-Ward will roll out this advertising and promotional efforts when it receives FDA approval and/or at the earliest opportunity thereafter.

36. Plaintiffs are informed and believe, and based thereon allege, that West-Ward will manufacture, advertise, promote, market, offer to sell and sell the West-Ward Tablet when it receives FDA approval and/or at the earliest opportunity thereafter.

37. Between 1972 and October 2010, West-Ward manufactured, advertised, promoted, marketed, and sold unapproved oral single-ingredient colchicine tablets that were very similar (if not identical) to the West-Ward Tablet. Plaintiffs are informed and believe, and based thereon allege, that West-Ward can and will use the same manufacturing facilities, advertising and marketing resources, and sales channels (that West-Ward previously used for its unapproved tablet) to manufacture, advertise, promote, market, offer for sale and sell the West-Ward Tablet.

Accordingly, Plaintiffs are informed and believe, and based thereon allege, that West-Ward has the capability and capacity to manufacturer, advertise, promote, market, offer to sell and sell the West-Ward Tablet when it receives FDA approval and/or at the earliest opportunity thereafter.

38. Plaintiffs are informed and believe, and based thereon allege, that West-Ward is preparing to solicit and receive orders for the West-Ward Tablet at the earliest opportunity once it receives FDA approval. Plaintiffs are informed and believe, and based thereon allege, that West-Ward will use the same resources that it used to solicit and receive orders from its unapproved oral single-ingredient colchicine tablet to solicit and receive orders for the West-Ward Tablet.

39. Plaintiffs are informed and believe, and based thereon allege, that West-Ward's financial projections for 2011 include revenues and profits that West-Ward projects it will obtain in 2011 from selling the West-Ward Tablet.

VI. West-Ward Will Induce Infringement of the Patents Because its Product Insert Will Recite the Methods Protected by the Patents

40. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has drafted a product insert that will accompany the West-Ward Tablet ("Product Insert").

41. Plaintiffs are informed and believe, and based thereon allege, that West-Ward (a) copied the methods of use protected by the Patents that are displayed on the COLCRYS® product insert and (b) included this copy in the Product Insert.

42. Plaintiffs are informed and believe, and based thereon allege, that the West-Ward Product Insert will contain dose modification recommendations to manage adverse events involving colchicine. These recommendations are methods of using colchicine that are protected by the Patents.

43. Plaintiffs are informed and believe, and based thereon allege, that the Product Insert will contain dose modification recommendations to avoid dangerous drug-drug interactions

involving colchicine. These recommendations are methods of using colchicine that are protected by the Patents.

44. Plaintiffs are informed and believe, and based thereon allege, that the Product Insert will contain dose modification information when colchicine is co-administered with certain antibiotics, for example, clarithromycin. This dose modification information is a method of using colchicine that is protected by the Patents.

45. Plaintiffs are informed and believe, and based thereon allege, that the Product Insert will contain dose modification information when colchicine is co-administered with certain HIV-1 protease inhibitors, for example, ritonavir. This dose modification information is a method of using colchicine that is protected by the Patents.

46. Plaintiffs are informed and believe, and based thereon allege, that the Product Insert will recite methods of use protected by the Patents and will induce infringement of one or more of the claims of the Patents.

47. Plaintiffs are informed and believe, and based thereon allege, that West-Ward will actively induce and encourage the infringement of one or more claims of the Patents because, among other things, its Product Insert will instruct medical workers and patients precisely how to use colchicine in a safe and effective manner.

48. Plaintiffs are informed and believe, and based thereon allege, that West-Ward intends for medical care workers and patients to use the West-Ward Tablet in a method that will infringe one or more claims of the Patents.

49. West-Ward's threat of infringement of one or more claims of the Patents is immediate and real.

COUNT I
(Declaratory Judgment of Infringement of the '004 Patent Under 35 U.S.C. § 271(b) against West-Ward)

50. Paragraphs 1 to 49 are incorporated herein as set forth above.

51. There is an actual and substantial controversy between Plaintiffs and West-Ward regarding the imminent infringement of the '004 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

52. Plaintiffs are informed and believe, and based thereon allege, that West-Ward's manufacture, use, sale, offer for sale, and/or importation of the West-Ward Tablet, as evidenced in its Product Insert, will induce infringement of one or more claims of the '004 Patent.

53. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the West-Ward Tablet before expiration of the '004 Patent.

54. Plaintiffs are entitled to a declaratory judgment that the future imminent manufacture, use, offer for sale, sale, and/or importation of the West-Ward Tablet before the patent expires will induce infringement of one or more claims of the '004 Patent.

COUNT II
(Declaratory Judgment of Infringement of the '758 Patent Under 35 U.S.C. § 271(b) against West-Ward)

55. Paragraphs 1 to 54 are incorporated herein as set forth above.

56. There is an actual and substantial controversy between Plaintiffs and West-Ward regarding the imminent infringement of the '758 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

57. Plaintiffs are informed and believe, and based thereon allege, that West-Ward's manufacture, use, sale, offer for sale, and/or importation of the West-Ward Tablet, as evidenced by its Product Insert, will induce infringement of one or more claims of the '758 Patent.

58. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the West-Ward Tablet before expiration of the '758 Patent.

59. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the West-Ward's Tablet before the patent expires will induce infringement of one or more claims of the '758 Patent.

COUNT III
(Declaratory Judgment of Infringement of the '681 Patent Under 35 U.S.C. § 271(b) against West-Ward)

60. Paragraphs 1 to 59 are incorporated herein as set forth above.

61. There is an actual and substantial controversy between Plaintiffs and West-Ward regarding the imminent infringement of the '681 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

62. Plaintiffs are informed and believe, and based thereon allege, that West-Ward's manufacture, use, sale, offer for sale, and/or importation of the West-Ward Tablet, as evidenced by its Product Insert, will induce infringement of one or more claims of the '681 Patent.

63. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the West-Ward Tablet before the expiration of the '681 Patent.

64. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the West-Ward Tablet before the patent expires will induce infringement of one or more claims of the '681 Patent.

COUNT IV
(Declaratory Judgment of Infringement of the '269 Patent Under 35 U.S.C. § 271(b) against West-Ward)

65. Paragraphs 1 to 64 are incorporated herein as set forth above.

66. There is an actual and substantial controversy between Plaintiffs and West-Ward regarding the imminent infringement of the '269 Patent, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

67. Plaintiffs are informed and believe, and based thereon allege, that West-Ward's manufacture, use, sale, offer for sale, and/or importation of the West-Ward Tablet, as evidenced by its Product Insert, will induce infringement of one or more claims of the '269 Patent.

68. Plaintiffs are informed and believe, and based thereon allege, that West-Ward has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the West-Ward Tablet before the expiration of the '269 Patent.

69. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the West-Ward Tablet before the patent expires will induce infringement of one or more claims of the '269 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request entry of judgment in its favor and against West-Ward as follows:

A. Declaring that the '004 Patent is valid and enforceable;

B. Declaring that the '758 Patent is valid and enforceable;

C. Declaring that the '681 Patent is valid and enforceable;

D. Declaring that the '269 Patent is valid and enforceable;

E. Declaring that under 35 U.S.C. § 271(b) West-Ward will infringe the '004 Patent;

F. Declaring that under 35 U.S.C. § 271(b) West-Ward will infringe the '758 Patent;

G. Declaring that under 35 U.S.C. § 271(b) West-Ward will infringe the '681 Patent;

H. Declaring that under 35 U.S.C. § 271(b) West-Ward will infringe the '269 Patent; and

I. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs demand a trial by jury on all issues that are triable as of right to a jury.

Dated: April 21, 2011

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is not the subject of any other action pending in this or any other court, or of any pending arbitration or administrative proceeding.

April 21, 2011

Brian M. English

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, declaratory relief.

April 21, 2011

Brian M. English